OCT 2 1 2004

K042209

510(k) Summary
Control Plasma N and P

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Donna Wolf Tel: 302-631-0384
Preparation date:	August 13, 2004

2. **Device Name/ Classification:**

Control Plasma N and Control Plasma P / Multipurpose system for in vitro coagulation studies, Class II (864.5425)

3. **Identification of the Legally Marketed Device:**

Control Plasma N (K023309) and Control Plasma P (K023312)

4. **Device Description:**

Control Plasma N is a lyophilized control prepared from pooled human plasma, stabilized with HEPES buffer solution. Control Plasma P is a lyophilized control prepared from pooled human plasma, adjusted to defined factor concentrations, and then stabilized with HEPES buffer solution.

5. **Device Intended Use:**

Control Plasma N is an assayed control for use in monitoring the performance of the following parameters in the normal range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Thrombin time (TT)
4. Batroxobin time
5. Fibrinogen
6. Coagulation factors II, V, VII, VIII, vWF, IX, X, XI, XII
7. Inhibitors: Antithrombin III, protein C, protein S, α2 –antiplasmin
8. Plasminogen
9. Lupus anticoagulants

Control Plasma P is an assayed control for use in monitoring the performance of the following parameters in the pathological range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (aPTT)
3. Fibrinogen (Clauss method)
4. Coagulation factors II, V, VII, VIII, vWF, IX, X, XI, XII
5. Inhibitors: Antithrombin III, protein C, protein S, α2 –antiplasmin
6. Plasminogen

6. **Medical device to which equivalence is claimed and comparison information:**

Control Plasma N (modified) and Control Plasma P (modified) are substantially equivalent in intended use to Control Plasma N (K023309) and Control Plasma P (K023312) currently marketed. The products differ from their predicate in that their value assignment process has changed for some of the reagents.

7. **Device Performance Characteristics:**

Control Plasma N and Control Plasma P values are substantially equivalent to the current legally marketed devices, K023309 and K023312.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 1 2004

Ms. Donna Wolf
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: k042209
Trade/Device Name: Control Plasma N and Control Plasma P
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: II
Product Code: GGN, GIZ, GGC
Dated: September 30, 2004
Received: October 8, 2004

Dear Ms. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042209

Device Name: Control Plasma N

Indications for Use:

Control Plasma N is an assayed control for use in monitoring performance of the following parameters in the normal range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (APTT)
3. Thrombin time (TT)
4. Batroxobin time
5. Fibrinogen
6. Coagulation factors II, V, VII, VIII, vWF, IX, X, XI, XII
7. Inhibitors: Antithrombin III, protein C, protein S, α2 –antiplasmin
8. Plasminogen
9. Lupus anticoagulants

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Indications for Use Statement

510(k) Number (if known): K042209

Device Name: Control Plasma P

Indications for Use:

Control Plasma P is an assayed control for use in monitoring the performance of the following parameters in the pathological range:

1. Prothrombin time (PT)
2. Activated partial thromboplastin time (aPTT)
3. Fibrinogen (Clauss method)
4. Coagulation factors II, V, VII, VIII, vWF, IX, X, XI, XII
5. Inhibitors: Antithrombin III, protein C, protein S, α2 –antiplasmin
6. Plasminogen

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Josephine Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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